GENERAL GUIDELINES FOR AQUATIC ANIMAL HEALTH SURVEILLANCE

Article X.X.X.1.

Introduction and objectives

1) In general, surveillance is aimed at demonstrating the absence of *disease* or *infection*, determining the occurrence or distribution of *disease* or *infection*, while also detecting as early as possible exotic or *emerging diseases*. The type of surveillance applied depends on the desired outputs needed to support decision-making. The following guidelines may be applied to all *diseases*, their agents and susceptible species as listed in this *Aquatic Code*, and are designed to assist with the development of surveillance methodologies. Except where a specific surveillance method for a certain *disease* or *infection* is already described in this *Aquatic Code*, the guidelines in this Appendix may be used to further refine the general approaches described for a specific *disease* or *infection*. Where detailed *disease/infection*-specific information is not available, suitable approaches should be based on the guidelines in this Appendix.

2) *Aquatic animal* health surveillance is an essential component necessary to detect diseases, to support claims for freedom from disease, to provide data to support the risk analysis process, and to substantiate the rationale for sanitary measures. Surveillance data underpin the quality of disease status reports and should satisfy information requirements for accurate risk analysis both for *international trade* as well as for internal decision-making.

3) Essential prerequisites to enable a Member Country to provide information for the evaluation of its *aquatic animal* health status are:

   a) that the particular Member Country complies with the provisions of Chapter 1.4.3. of this *Aquatic Code* on the evaluation of *Competent Authorities*;

   b) that surveillance data, where possible, be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);

   c) that transparency in the planning and execution of surveillance activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.2.1. of this *Aquatic Code*.

4) The objectives of this Appendix are to:

   a) provide guidance to the type of outputs that a surveillance system should generate;

   b) provide guidelines to assess the quality of disease surveillance systems.

Article X.X.X.2.

Definitions

The following definitions apply for the purposes of this Appendix.

Bias: A tendency of an estimate to deviate in one direction from a true value.

Case definition: A case definition is a set of criteria used to classify an *aquatic animal* or epidemiological unit as a case.

Confidence: In the context of demonstrating freedom from *infection*, confidence is the probability that the type of surveillance applied would detect the presence of *infection* if the population were infected. The confidence depends on, among other parameters, the assumed level of *infection* in an infected population. The term refers to our confidence in the ability of the surveillance applied to detect *disease*, and is equivalent to the sensitivity of the surveillance system.

Early detection system: Means an efficient system for ensuring the rapid recognition of signs that are suspicious of a *listed disease*, or an *emerging disease* situation, or unexplained mortality, in *aquatic animals* in an *aquaculture establishment* or in the wild, and the rapid communication of the event to the *Competent Authority,* with the aim of activating diagnostic investigation with minimal delay. Such a system should include the following characteristics:

a) broad awareness, e.g. among the personnel employed at *aquaculture establishments* or involved in *processing*, of the characteristic signs of the *listed diseases* and *emerging diseases*;

b) veterinarians or *aquatic animal* health specialists trained in recognising and reporting suspicious disease occurrence;

c) ability of the *Competent Authority* to undertake rapid and effective disease investigation;

d) access by the *Competent Authority* to laboratories with the facilities for diagnosing and differentiating *listed* and *emerging diseases*.

Epidemiological unit: A group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogen. This may be because they share a common aquatic environment (e.g. fish in a pond, caged fish in a lake, mollusc rearing units, shrimp ponds), or because of common management practices. In some circumstances, the epidemiological unit may be a single such unit, or group of such units, on the same farming site.

Outbreak definition: An outbreak definition is a set of criteria used to classify the occurrence of one or more cases in a group of animals or units as an outbreak.

Probability sampling: A sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

Sample: The group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide surveillance information.

Sampling units: The unit that is sampled, either in a random survey or in non-random surveillance. This may be an individual animal or a group of animals (e.g. an epidemiological unit). Together, they comprise the sampling frame.

Sensitivity: The proportion of true positive tests given in a diagnostic test, i.e. the number of true positive results divided by the number of true positive and false negative results.

Specificity: The probability that absence of infection will be correctly identified by a diagnostic test (i.e. the number of true negative results divided by the number of true negative and false positive results).

Study population: The population from which surveillance data is derived. This may be the same as the target population or a subset of it.

Surveillance: Means a systematic series of investigations of a given population of *aquatic animals* to detect the occurrence of *disease* for control purposes, and which may involve testing samples of a population.

Surveillance system: A method of surveillance that may involve one or more component activities that generates information on the health, disease or zoonosis status of animal populations.

Survey: An investigation in which information is systematically collected, usually carried out on a sample of a defined population group, within a defined time period.

Target population: The population about which conclusions are to be inferred.

Test: A procedure used to classify a unit as either positive, negative or suspect with respect to an *infection* or *disease*.

Test system: A combination of multiple tests and rules of interpretation which are used for the same purpose as a test.

Article X.X.X.3.

Principles of surveillance

1) Types of surveillance

a) Surveillance may be based on many different data sources and can be classified in a number of ways, including:

i) the means by which data are collected (active versus passive surveillance);

ii) the disease focus (pathogen-specific versus general surveillance); and

iii) the way in which units for observation are selected (structured surveys versus non-random data sources).

b) In this Appendix, surveillance activities are classified as being based either on:

i) structured population-based surveys, such as:

– systematic sampling at slaughter;

– random surveys; or

ii) structured non-random surveillance activities, such as:

– disease reporting or notifications;

– control programmes/health schemes;

– targeted testing/screening;

– ante-mortem and post-mortem inspections;

– laboratory investigation records;

– biological specimen banks;

– sentinel units;

– field observations;

– farm production records.

2) Surveillance data

In addition, surveillance data should be supported by related information, such as:

a) data on the epidemiology of the infection, including environmental, host population distribution, and climatic information;

b) data on animal movements and trading patterns for animals and animal products;

c) history of imports of potentially infected material; and

d) biosecurity measures in place.

The sources of evidence should be fully described. In the case of a structured survey, this should

include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

3) Critical elements

In assessing the quality of a surveillance system, the following critical elements need to be addressed over and above quality of *Competent Authorities* (Chapter 1.3.4.).

a) Populations

Surveillance should be carried out in such a way as to take into account all *aquatic animal* species susceptible to the *infection* in a country, *zone* or *compartment*. The surveillance activity may cover all individuals in the population or part of them. In the latter case, care should be taken regarding the inferences made from the results.

Definitions of appropriate populations should be based on the specific recommendations of the disease chapters of this *Aquatic Code*.

b) Epidemiological unit

The relevant epidemiological unit for the surveillance system should be defined and documented to ensure that it is representative of the population. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

c) Clustering

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of moribund fish in a pond, a cluster of ponds in a farm, or a cluster of farms in a *zone* or *compartment*). Clustering should be taken into account in the design of surveillance activities and the statistical analysis of surveillance data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection*.

d) Case and outbreak definitions

Clear and unambiguous case and outbreak definitions should be developed and documented for each pathogen under surveillance, using, where they exist, the standards in this *Aquatic Code*.

e) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of surveillance data should be flexible to deal with the complexity of real-life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant pathogens, varying production and surveillance systems, and types and amounts of data and information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be documented and supported by references to the OIE Standards, to the scientific literature and other sources, including

expert opinions. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

f) Testing

Surveillance involves the detection of *disease* or *infection* by the use of appropriate case definitions based on the results of one or more tests for evidence of infection or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity. Imperfect sensitivity and/or specificity will have an impact on the conclusions from surveillance and should be taken into account in the design of surveillance systems and analysis of surveillance data.

The values of sensitivity and specificity for the tests used should be specified, and the method used to determine or estimate these values should be documented. Where values for sensitivity and/or specificity for a particular test are specified in the *Aquatic Manual*, these values may be used without justification.

Samples from a number of animals or units may be pooled together and subjected to a single test. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

g) Quality assurance

Surveillance systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

h) Validation

Results from animal health surveillance systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

i) Data collection and management

The success of a surveillance system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

i) the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location;

ii) the ability of the data processing system to detect missing, inconsistent or inaccurate

data, and to address these problems;

iii) maintenance of disaggregated data rather than the compilation of summary data;

iv) minimisation of transcription during data processing and communication.

Article X.X.X.4.

Principles for surveys

In addition to the general principles for surveillance discussed above, the following guidelines should be used when planning, implementing and analysing surveys.

1) Types of surveys

Surveys may be conducted on the whole target population (i.e. a census) or on a sample. A sample may be selected in either of the two following manners:

a) non-probability-based sampling methods, such as:

i) convenience;

ii) expert choice;

iii) quota;

b) probability-based sampling methods, such as:

i) simple random selection;

ii) cluster sampling;

iii) stratified sampling.

2) Systematic selection

Periodic or repeated surveys conducted in order to document disease freedom must be done using probability-based sampling methods so that data from the study population can be extrapolated to the target population in a statistically valid manner.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be made of any biases that may be inherent in the survey design.

3) Survey design

The population of epidemiological units should first be clearly defined where after sampling units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure of the population being studied, the epidemiology of the infection and the resources available.

4) Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the object of the study, such as the presence or absence of *infection*. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical

constraints imposed by different environments and production systems. In order to detect the presence of an *infection* in a population of unknown disease status, targeted sampling methods that optimise the detection of *infection* can be used. In such cases, care should be taken regarding the inferences made from the results.

5) Sampling methods

When selecting epidemiological units from within a population, a formal probability sampling method (e.g. simple random sampling) should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

In any case, the sampling method used at all stages should be fully documented and justified.

6) Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. *infection*) or to estimate a parameter (e.g. the prevalence of *infection*). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Article X.X.X.5.

Principles for structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys. There is a wide variety of non-random data sources that can be used.

1) Common non-random surveillance sources

A wide variety of non-random surveillance sources may be available. These vary in their primary purpose and the type of surveillance information they are able to provide. Some systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from *infection*. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. disease reporting systems, sentinel sites, testing schemes).

a) Disease reporting or notification systems

Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for risk analysis, or for early detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a good specificity.

b) Control programmes/health schemes

Aquatic animal disease control programmes or health schemes, while focusing on the control or eradication of specific diseases, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured surveillance.

c) Targeted testing/screening

This may involve testing targeted to selected sections of the population (sub-populations), in which disease is more likely to be found. Examples include testing culled animals, weak animals (often at the water outlet or on the water surface) and recently-dead animals.

d) Ante-mortem and post-mortem inspections

Inspections of *aquatic animals* at harvesting, slaughtering and processing premises may provide valuable surveillance data. The sensitivity and specificity of such inspections for the detection of *disease* will be influenced by:

i) the level of training and experience of the staff doing the inspections, and the ratio of staff of different levels of training;

ii) the involvement of the *Competent Authorities* in the supervision of ante-mortem and post-mortem inspections;

iii) the quality of construction of the slaughtering and processing premises, speed of the slaughter chain, lighting quality, etc.; and

iv) staff morale.

Inspections of *aquatic animals* at harvesting, slaughtering and processing premises are likely to provide good coverage only for particular age groups and geographical areas. Statistical biases are likely to be more frequent for infected animals originating from larger, better managed farms rather than for animals originating from smallholder or backyard farms, as well as for healthy rather than diseased animals.

Both for traceback in the event of detection of disease and for analysis of spatial and farm-level coverage, there should be, if possible, an effective identification system that relates each batch of *aquatic animals* in the slaughtering or processing premises to its property of origin.

e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. As with inspections of fish slaughtering premises, there needs to be a mechanism to relate specimens to the farm of origin.

f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection*, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

g) Sentinel units

Sentinel units/sites involve the identification and regular testing of one or more of animals of known health/immune status in a specified geographical location to detect the occurrence of disease (usually serologically). They are particularly useful for surveillance of diseases with a strong spatial component, such as diseases with an intermediate host. Sentinel units provide the opportunity to target surveillance depending on the likelihood of

infection (related to intermediate host habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from *infection*, or provide data on prevalence and incidence as well as the distribution of *disease*.

h) Field observations

Clinical observations of animals in the field are an important source of surveillance data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of *disease* at the rearing unit level. In general, the sensitivity of this approach may be quite high (depending on the disease), but the specificity is often quite low.

2) Critical elements for structured non-random surveillance

There is a number of critical factors which should be taken into account when using structured non-random surveillance data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. Surveillance data from non-random data sources may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

3) Analytical methodologies

Different methodologies may be used for the analysis of non-random surveillance data.

Analytical methodologies based on the use of step-wise probability estimates to describe the surveillance system may determine the probability of each step either by:

a) the analysis of available data, using a scientifically valid methodology; or where no data are available;

b) the use of estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology.

4) Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented including references to published material.

Surveillance information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of *aquatic animal* health status. Such evidence gathered over time may be combined to provide an overall level of confidence. For instance, repeated annual surveys may be analysed to provide a cumulative level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources may be able to achieve the same level of confidence in just one year.

Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account.

Article X.X.X.6.

Demonstration of freedom from disease

1) Introduction

A surveillance system to demonstrate freedom from *disease* should meet the following requirements in addition to the general requirements for surveillance outlined in point 2) of this Article.

Freedom from *disease* implies the absence of the *disease agent* in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *disease*. Demonstrating freedom from *disease* involves providing sufficient evidence to demonstrate the *disease agent* is not present in a population. In practice, it is not possible to prove (i.e. be 100% confident) that a population is free from *disease* (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *disease*, if present, is present in less than a specified proportion of the population.

However, finding evidence of infection at any level in the target population automatically invalidates any freedom from infection claim.

Evidence from non-random data sources as stated below, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared with structured surveys.

2) Self-declaration of freedom from disease

This point provides general principles for declaring a country, *zone* or *compartment* free from *disease* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this point are based on Articles X.X.X.1., X.X.X.2. and X.X.X.3. of this Appendix and the following assumptions:

a) in the absence of *disease* and vaccination, the *aquatic animal population* would become susceptible over a period of time; and

b) the *disease agents* to which these provisions apply are likely to produce identifiable clinical signs in *susceptible aquatic animals*; and

c) *Competent Authorities* will be able to investigate, detect, diagnose and report *disease*, if present; and

d) the absence of *disease* over a long period of time in a *susceptible* population can be substantiated by effective disease investigation and reporting by the *Competent Authorities* of an OIE Member Country.

3) Additional requirements to declare a country, zone or compartment free from disease without targeted surveillance

a) Historically free

Unless otherwise specified in the relevant disease chapter, a country, *zone* or *compartment* may be declared free from *disease* without applying a *targeted surveillance* programme when:

i) there has never been any observed occurrence of *disease*; or

ii) eradication has been achieved or the *disease* has not been observed for at least 25 years,

provided that for at least the past 10 years:

iii) it has been a notifiable disease; and

iv) an early detection system has been in place; and

v) measures to prevent *disease* introduction have been in place; and

vi) the *disease* is not known to be established in wild populations within the country or *zone* intended to be declared free. (A country or *zone* cannot be declared historically free if there is any evidence of the *disease* in wild populations.)

b) Last occurrence within the previous 25 years

Countries, *zones* or *compartments* that have achieved eradication (or in which the disease has ceased to occur) within the previous 25 years, should follow the *targeted surveillance* requirements in this *Aquatic Code* if they exist. In the absence of specific requirements for surveillance in this *Aquatic Code*, countries should follow these general guidelines for surveillance. To demonstrate free status, the following must have been in place continuously for at least the past 10 years:

i) the *disease* has been a *notifiable* disease; and

ii) an early detection system has been in place; and

iii) measures to prevent *disease* introduction have been in place; and

iv) the *disease* is not known to be established in wild populations within the country or *zone* intended to be declared free. (A country or *zone* cannot be declared historically free if there is any evidence of the *disease* in wild populations.)

c) Guidelines for the discontinuation of *targeted surveillance* after declaration of freedom from disease

A country, *zone* or *compartment* that has been *declared free* from *disease* following the provisions of this *Aquatic Code* may discontinue *targeted surveillance* while maintaining the disease-free status provided that:

i) the *disease* remains notifiable; and

ii) an early detection system remains in place; and

iii) measures to prevent *disease* introduction remain in place.

Article X.X.X.7.

Surveillance for determining occurrence and distribution of disease

Surveillance for occurrence and distribution of *disease* or of other relevant health-related events is widely used to assess progress in the control or eradication of selected diseases and pathogens and an aid to decision making.

In contrast to surveillance to demonstrate freedom from *disease*, surveillance used to assess progress in control or eradication of selected diseases and pathogens is usually designed to collect data about a number of variables of *aquatic animal* health relevance, for example:

1) prevalence or incidence of *infection*;

2) morbidity and mortality rates;

3) frequency of *disease*/*infection* risk factors and their quantification when the risk factors are expressed by continuous (real numbers) or discrete (integers) variables;

4) frequency distribution of population sizes or the sizes of other epidemiological units;

5) frequency distribution of antibody titres;

6) proportion of immunised animals after a vaccination campaign;

7) frequency distribution of the number of days elapsing between suspicion of infection and laboratory confirmation of the diagnosis and/or to the adoption of control measures;

8) farm production records, etc.

All of the listed data may also have relevance for the risk analysis.